International Journal of All Research Education and Scientific Methods (IJARESM),
ISSN: 2455-6211, Volume 13, Issue 5, May-2025, Available online at: www.ijaresm.com

Formulation and Evaluation of Transdermal Patch from Ashwagandha Extract

Ms. Samiksha Pramod Thorat[1], Ms. Anishka Ravindra Sonawane[2], Proff. Jagdale Ashok[3]

[1,2,3]Nandkumar Shinde College of Pharmacy, AghurVaijapur- 423701
Dist. Chh. Sambhajinagar Maharashtra

----------**********----------

ABSTRACT

Transdermal patches are a type of drug delivery system that delivers medication through the skin and into the bloodstream.The formulation of herbal transdermal patches involves selecting appropriate herbs that have wound healing properties and incorporating them into a patch.The transdermal patches with the incorporation of herbal extract of Ashwagandha extract.

Keywords : Transdermal Drug Delivery System, Biocompatibility, Drug Reservoir.

INTRODUCTION

In order to increase therapeutic efficacy and decrease side effects, transdermal drug delivery systems use self-contained, discrete dosage forms of patches to administer medications topically. These patches then release the drug into the systemic circulation at a predetermined and controlled rate over an extended period of time. One kind of drug delivery method that gets medication into the bloodstream through the skin is a transdermal patch. Particularly, herbal transdermal patches are a new field of study since they provide a safe, all-natural method of delivering medicinal substances to the body.
One type of alternative medicine is herbal transdermal patches, which apply herbal treatments directly to the skin. The natural components in the patches, which are worn topically, are released gradually into the body over time.

Advantages of Transdermal Drug Delivery System

1. This approach is highly practical for the drug delivery system.
2. It provides a consistent plasma level, just as intravenous infusion.
3. It works well with traditional dose forms.
4. It lessens variations in the pharmacological and physiological response.
5. Because of the lower plasma concentration, it lessens adverse effects.
6. It is useful for delivering medications with low therapeutic index and short biological half-lives.
7. Using a medication with a low melting point is beneficial.
8. It makes stopping medication therapy simple at any time.
9. If a patient is experiencing diarrhea or vomiting, oral medications may be administered as a transdermal patch.
10. It circumvents the inconvenience of the parenteral method and is non-invasive.
11. It offers prolonged treatment with just one use.

Disadvantages of Transdermal Drug Delivery System :

Transdermal drug delivery systems, while innovative, have certain limitations:

1. **Skin Irritation:** The drug, adhesive, or excipients in the patch can cause rashes, local irritation, erythema, or contact dermatitis.
2. **Drug Properties:** Only drugs with specific physicochemical properties, such as lipophilic character, can effectively penetrate the skin.
3. **Limited Dose Delivery:** High doses of drugs are challenging to deliver through this method.

Structure of skin :

skin is broadly segregated into three layers such as :

1. **Epidermis :** Superficial, thinner portion of epithelial tissue.
2. **Dermis :** Deeper thicker connective tissue.

3. **Hypodermis :** Deep to the dermis, but not exactly the part of skin, is the subcutaneous layer composing areolar and adipose tissue.

Skin appendages includes eccrine sweat glands, apocrine glands, sebaceous glands and hair (fig : 1.1).

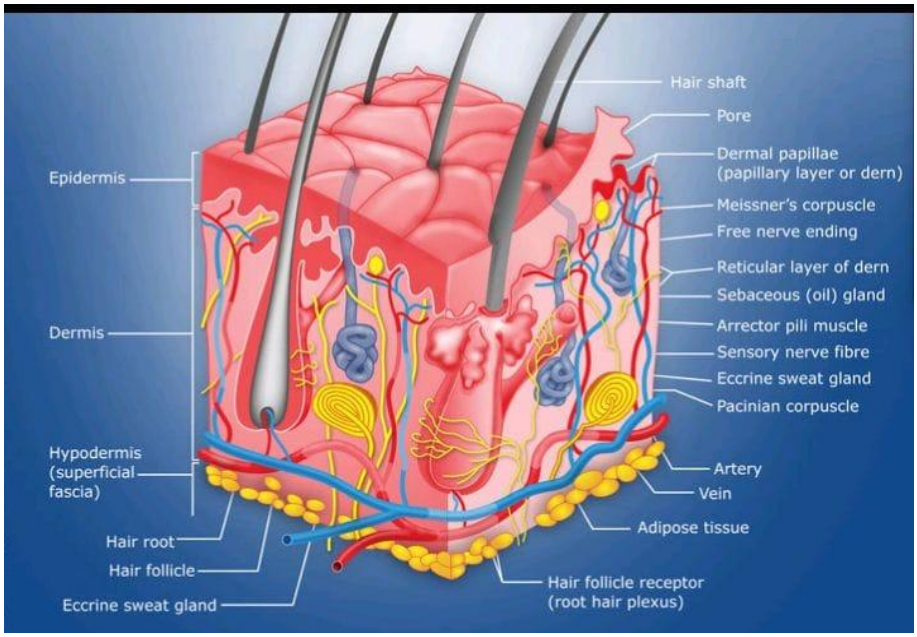


Fig : 1.1 : Diagrammatic representation of Anatomy of skin

1. Epidermis :

It is the uppermost multi layer of the skin, composed of stratified keratinised squamous epithelium. It contain four cells, such as keratinocytes (90%), melanocytes, Langerhans cells and merkel cells. The epidermis divided into five sub layers namely.

i. Stratum corneum (horny layer).
ii. Stratum lucidum.
iii. Stratum granulosum (granular layer).
iv. Stratum spinosum (prickly layer).
v. Stratum germinativum (basal layer of dermoepidermal junction).

Stratum corneum : it is the most differentiated top superficial layer of keratinised cells (corneocytes). It consists of 25 to 30 layer of flattened keratinocytes that contain mostly keratin. The nuclei are absent. Between the cells are lipids from lameller granules that forms major constituents for water barrier of the skin. (fig. 1.2). These multiple layers act as protective for the deeper layer from injury and microbial abrasion.

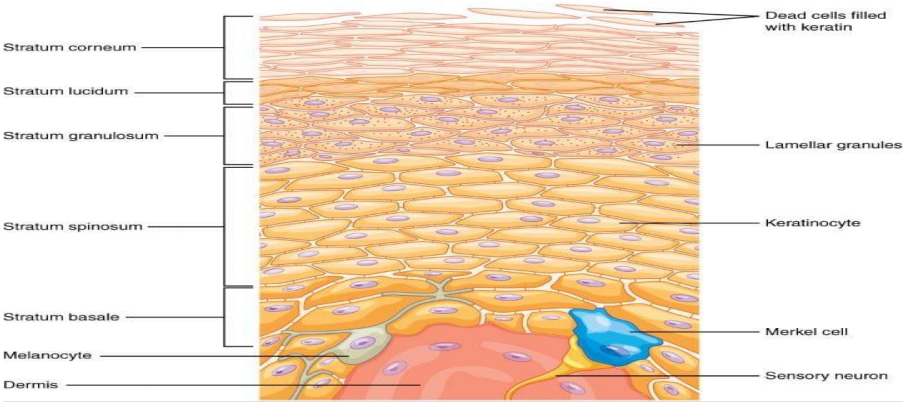


Fig : 2 : Epidermis Layers And Cells.

i. **Stratum lucidum :** it is thin, more or less transparent, glistering layer. It is present only in the thick skin of fingertips, palms and soles.

ii. **Stratum granulosum :**It is a layer beneath the stratum lucidium.In addition to irregularly shaped, non-membrane-bound keratohyalin granules, this contains or has three to five layers of flat cells. This granule contains organized protein profiles that are involved in the skin's barrier function and keratinization.

iii. **Stratum spinosum :** these is broad layer.The cell flatten and their nuclei shrink, and look like polygonal, thus also called as polygonal cells.

iv. **Stratum germinative or basale :** it is the deepest layer of the epidermis where basal cells are non nucleated, columnar and about 6 um wide with their long axis at right angles to the dermoepidermal junction. It is also called as stratum germinativum junction. It is also called as stratum germinativum due to mitotic active cells which constantly proliferating the skin and renew the epidermis providing constant thickness and healthy balanced skin.

Dermis : The dermis is made up of a network of collagen and elastin fibers embedded in a matrix of mucopolysaccharides that includes lymphatic nerve terminals, blood arteries, and other structures.

Drug permeation through skin: The sebaceous gland and follicular epithelium allow the drug to be absorbed. Diffusion across the intact stratum corneum then takes place after the steady state is reached. There are two ways for drugs to enter the skin:

1. through two other routes, such as transcellular and intercellular. Trans epidermal pathway: If the drug enters the body through this route, it enters the body

2. Trans follicular: In this case, the medicine is delivered through the hair follicles and sweat glands. Despite having a high permeability, this route is not very significant.

Transdermal patch

Transdermal patches are adhesive patches that are mediated and coated with a medicine. They are applied to the skin to allow the drug to enter the bloodstream through the skin. In addition to improving patient convenience, delivery technologies such as TDDS also improve drug efficacy and safety. The primary purpose of transdermal patches is to administer medication through the skin, which diffuses across the different layers of the skin and enters the bloodstream, or systemic circulation.

TDDS patches are self-contained dosage forms that, when applied topically, allow the drug to enter the body through the skin and enter the bloodstream at a regulated pace over an extended period of time.

Fig : 3 : transdermal patch

Mechanism of Transdermal patches

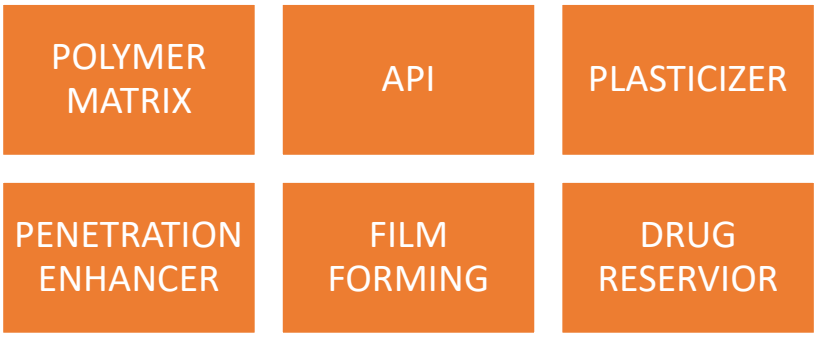
Transdermal patches are adhesive patches applied to the skin to deliver medication directly into the bloodstream. They work through a controlled drug delivery system that bypasses the digestive system, offering consistent and prolonged release of medication.

The mechanism involves three main layers:

1. **Drug Reservoir:** Contains the medication.
2. **Adhesive Layer:** Ensures the patch adheres to the skin.
3. **Backing Layer:** Protects the patch and prevents drug loss.

The medication is released gradually, either through a porous membrane or by body heat melting thin layers of medication embedded in the adhesive. This method is particularly useful for drugs with small molecules that can penetrate the skin barrier.

Constituent for Transdermal patches :



1 . Polymer matrix :
This mostly involves the release of the medicine from transdermal patches that are dependent on or controlled by the polymer. As the polymer concentration rises, a very dense matrix is formed, which slows the drug's release rate. The foundation of a transferable drug delivery system is made up of polymers. The concentration and other physical and chemical characteristics of the drug and polymer determine the drug's diffusion across the polymer matrix and release rate.

The optimal characteristics of active ingredients include:

1. **Biocompatibility:** The polymer should be non-toxic and non-irritating to the skin.
2. **Controlled Drug Release:** It should allow for a consistent and controlled release of the drug over time.
3. **Adhesion:** The polymer should adhere well to the skin without causing discomfort or leaving residues.
4. **Flexibility and Strength:** It should be flexible enough to conform to the skin's surface while maintaining structural integrity.
5. **Permeability:** The polymer should facilitate the drug's diffusion through the skin layers.
6. **Stability:** It should be chemically and physically stable under storage and usage conditions.
7. **Ease of Manufacturing:** The polymer should be easy to process and cost-effective for large-scale production.

Example for Polymer matrix :

1. Gelatin.
2. HPMC (Hydroxypropyl methyl cellulose).
3. PVA (polyvinyl alcohol).
4. PVC (polyvinyl chloride).
5. Starch.
6. PVP.
7. Polyethylene.

2 . Active Pharmaceutical Ingredients :
The most crucial part of transformer patches is the drug reservoir. It needs to be chosen with extreme caution. Since ionized drug molecules have poor skin permission and penetration, drugs that dissolve quickly are the best agents for creating transformative patches.

The optimal characteristics of active ingredients include:

1. Being non-toxic.
2. Having a short biological half-life.
3. Being strong enough to produce the necessary pharmacological action.
4. Not exhibiting any kind of hypersensitivity reaction when administered.
5. Not being toxic; The drug should have an affinity for both the lipophilic and hydrophilic phases.

3 . Permeation enhancer :
These are the compounds that increase the permeability of the skin by improving the polar, nonpolar, and polar-nonpolar drug penetration pathways on the skin.

If one of these paths is changed, penetration is increased. Non-polar pathways can be changed by changing the lipids' stiffness, while polar pathways can be changed by altering the conformation of proteins.

The ideal penetration enhancer properties are:

1. The skin layer shouldn't sustain any long-term harm.
2. Pharmacological inertness
3. nontoxicity
4. nonallergy
5. action specificity
6. and nonirritability are qualities that it should possess.

4 . Plasticizer :
In a transdermal patch, a plasticizer is a substance added to the patch's matrix or adhesive to enhance its flexibility, workability, and overall performance.

Ideal Properties of a Plasticizer:

1. High plasticizing efficiency
2. Good compatibility
3. Low volatility.
4. Non-toxicity
5. Stability.
6. Low migration.
7. Good solvating power

Some common plasticizers used in transdermal patches include:

1. Dibutyl phthalate (DBP)
2. Dibutyl sebacate (DBS)
3. Triethyl citrate (TEC)
4. Triacetin (TA)
5. Polyethylene glycol (PEG)

5. Film former :
A thin, flexible film containing the active pharmaceutical ingredient (API) and regulating its release is made using a film-forming polymer.

Ideal Film-Forming Polymer Characteristics for a Transdermal Patch:

1. Good film-forming ability: The capacity to create a consistent, thin film.
2. Strong tensile strength: Able to withstand tearing and shattering.
3. Good flexibility: Capacity to adapt to the surface of the skin.
4. Low water vapor transmission rate (WVTR): Preserves patch integrity and reduces moisture loss.
5. Good chemical stability: Able to withstand deterioration or reactivity with other patch components or the API.
6. Biocompatibility: Skin-non-irritating and non-toxic.
7. Strong adhesion: Forms a strong bond with the skin and other patch elements.
8. Thickness adjustment: Enables the ideal patch thickness and API release.
9. Good optical clarity: Visible inspection is possible due to transparency or transparency.
10. Low residual solvents: Reduces the possibility of toxicity or skin irritation.

The following are some typical film-forming polymers found in transdermal patches:
1. Polyvinylpyrrolidone (PVP).
2. Polyvinyl alcohol(PVA).
3. Polyethylene oxide.
4. Polyurethane.
5. Ethyl cellulose.

International Journal of All Research Education and Scientific Methods (IJARESM),
ISSN: 2455-6211, Volume 13, Issue 5, May-2025, Available online at: www.ijaresm.com

6. Drug reservoir :

Drug reservoirs: this is a component that contains one polymer or the combination of polymers in various different concentrations and ratios.

2. Information of Ashwagandha :

Sr. No	Particular	
1.	**Name**	Ashwagandha
2.	**Figure**	**Fig : 4 : Ashwagandha**
3.	**Synonym**	Withania somnifera
4.	**Biological Source**	Ashwagandha consist of dried roots and occasionally the leaves of Withania somnifera
5.	**Family**	Solaneaceae
6.	**Chemical Constituent**	Withanoloids, Alkaloids(Withaninsomniferin), Saponin, Flavonids and Tannin
7.	**Pharmacological action**	Anti-stress, anti-inflammatory, antioxidant and neuroprotective activities
8.	**Category**	Adaptive
9.	**Formula**	C56H78O12S

Materials and Methods :

Instruments : Magnetic Stirrer, Ph meter, Desiccator, Weighing balance.

Fig : 5 : Desiccator.

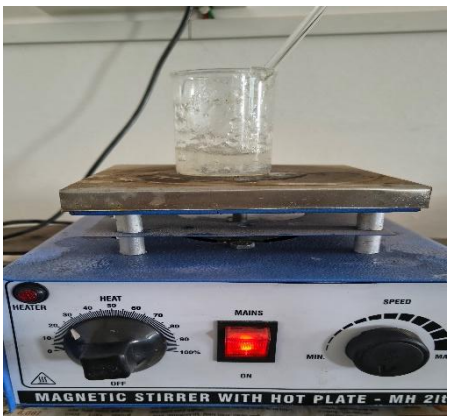


Fig : 6 : Magnetic stirrer.

Fig : 7 : PH meter.

Fig : 8 : Weighing balance.

Apparatus : Measuring cylinder, Glass rod, Petri dish, Beaker.

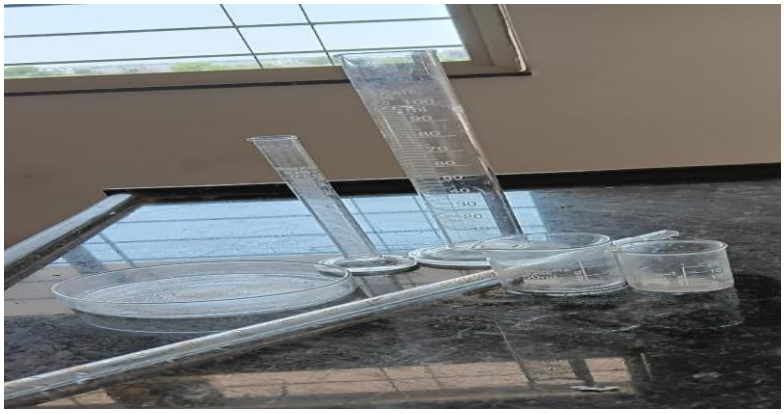


Fig : 9 : Apparatus.

Chemicals : PVA, HPMC, Glycerine, Oleic acid, Eucalyptus oil, Ethanol,

Fig : 10 : Chemicals

Content :

Ingredients	Quantity	Purpose
Ashwagandha extract	100 mg /patch	Active Ingredient
HPMC	1 g	Film forming polymer
PVA	1 g	Film strength enhancer
Oleic acid	0.5 ml	Permeation enhancer
Eucalyptus Oil	0.2 ml	Neutral penetration enhancer and fragrance
Glycerin	2 ml	Humectant and flexibility enhancer
Solvent (ethanol : water =70 : 30 v / v)	20ml	Dissolution medium

4. Procedure for formulation of Transdermal patches :

1. **Preparation of the Polymer Matrix**
   a. Weigh HPMC K4M and PVA in the given quantity.
   b. Slowly add Ethanol : Water (70 : 30 v/v) mixture while stirring with a magnetic stirrer at for 30 minutes until complete dispersion is achieved.
   c. Add Glycerine to the polymer solution and stir for another 30 minutes to achieve homogeneity.
2. **Incorporation of Active Ingredient and enhancers :**
   d. Dissolve Ashwagandha extract in oleic acid and eucalyptus oil and mix it well for 15 minutes.
   e. Add this solution to the polymer matrix and continue stirring for 1 hour.
3. **Casting and Drying of the Patch :**
   f. Pour the final solution in Petri dish and spread uniformly to achieve 0.2 mm thickness.
   g. Allow air drying at room temperature for 24 hours or use an oven at 40 degree C for 6 hours for faster drying .
4. **Cutting and final Processing :**
   h. Cut drying film into 15 mm x 15 mm patches using a sharp cutter.
   i. Store patches in sealed aluminium pouches to prevent moisture absorbtion.

Fig : 11 : Content in petri dish

5. Evaluation Test for Prepared Transdermal patch :

1. Organoleptic Characteristics.
2. Ph determination.
3. Phytochemical Screening of Ashwagandha extract.
4. Measurement of thickening of patches.
5. % of moisture content.

Results of Evaluation Test :

1. **Results of Organoleptic Test :**

Sr. No	Charecteristic	Observation
1.	Colour	Whitish cream
2.	Texture	Smooth and Uniform
3.	Appearance	Turbid
4.	Odour	Aromatic

2. **Result of Ph :**
The Ph of Formulated Patches was found to be Range of **5-9 .**

3. **Results for phytochemicals screening of Ashwagandha :**

Sr. No	Name of Chemical Test	Procedure	Result
1.	**Mayer's Test**	To 1.0 ml of the filtrate, 2 ml of thereagent was added. Formation of white or pale precipitate shows the presence of alkaloids.	+
2.	**Wagner's Test**	To about 1-2 ml of the filtrate, 2ml of Wagner's reagent was added. Reddish brown colored precipitate indicates the presence of alkaloids.	+
3.	**Hanger's Test**	The acetic test solution treated withHager's reagent (Saturated picric acid solution) gives yellow precipitate.	+
4.	**Dragendroff's Test**	The filtrate was treated with Dragendorff's reagent and the formation of orange precipitate indicates the presence of alkaloids.	+

4. **Measurement of thickening of patches :**
The Thickness of Formulated transdermal patches were evaluated to be 0.22mm using Vernier calliper. Thickness was evaluated by measuring the average thickness of three sites of the patches.

5. **Results for % of moisture content :**
Here,

Initial weight is 0.6gm and Final weight is 0.3gm So, by using the formula of % MC

Moisture Content (%)=Initial weight – Final weight / Final weight*100

%MC = (0.6 – 0.3) / 0.6*100 = 50%

Hence the %Moisture Content was evaluated to be = **50%**

6. Result of formulated transdermal patch :

Fig : 12: Formulated transdermal Patch

CONCLUSION

The transdermal patches with the incorporation of herbal extract of Ashwagandha were formulated. As earlier it was discussed that now in the emerging world there is a more demand for herbal formulations. In the latest research studies it has become apparent that there is a wide scope for implementation of novel Drug delivery systems as we all are aware of some over-powering benefits of novel Drug delivery systems over the traditional Drug delivery systems. As it is concerned with the drug delivery through the skin. The transdermal drug delivery system has an effective benefit over the topical method of drug delivery. The advancement in the drug delivery system is allowing a wide range of drugs to be administered through the Transdermal Drug delivery system.

The herbal transdermal patches including Ashwagandha were aimed to heal the wound or any type of injury or the skin infection like eczema etc. In the various research it's seen that transdermal drug delivery systems have great scope in future for developing drug delivery systems in NDDS. Transdermal Drug delivery system is widely accepted now-a-days because it causes the drug penetration through skin layers and reaches systemic circulation without causing any damage to skin or rupturing it. TDDS also benefits for controlled release of drug for prolonged period of time. More research and innovation will bring the wide acceptance in the use of various other transdermal drug delivery systems like iontophoresis, Ultrasound Technology, Med Tat etc.

REFERENCES

[1]. Formulation and evaluation of herbal transdermal patches in treatment of wound healing Volume7 issue 9, ISSN: 2455-2631.
[2]. Viswesari G, Christopher R, Rajendra W. Phytochemical screening of active secondary metabolites present in Withania somnifera root: role in traditional medicine. Int J Pharm Sci Res. 2013;4(7):2770-2776.
[3]. Dr. Prajapati T.S., Dr. Manivannan R., (Prof.) Dr. Ramesh G.K. ―novel drug delivery system‖ chapter 6th, page number 11
[4]. Dhanani T, Shah S, Gajbhiye N, Kumar S. Effect of extraction methods on yield , phytochemical constituents and antioxidant activity of Withania somnifera. Arab J Chem. 2017;10(01):1193-1199.
[5]. World general of pharmaceutical research volume 6, issue 13, 365-374 research article.
[6]. Formulation and evaluation of herbal transdermal patches in treatment of wound healing Volume7 issue 9, ISSN: 2455-2631
[7]. Tulsi- a review based upon its ayurvedic and modern therapeutic uses, volume 8;issue5; E-ISSN 2349-9788: P ISSN 2454-2237
[8]. The effect of aloe vera on wound healing in cell proliferation, migration and viability Eric Tiplicki PMID:30256753.
[9]. The difference between Topical and Transdermal Medication. White Paper by Robert L Wilber, PharmD Executive director, Medical Affairs, and Gensco Pharma
[10]. The effect of Aloe vera on wound healing in cell proliferation, migration and viability Eric Tiplicki PMID: 30256753
[11]. Rosenberg L Z, Wound healing, growth factors, emedicine, 2006.
[12]. Vinotha S, Thanbrew I, Sri Ranjani S. Phytochemicals screening of various exrtract of root of withania somnifera (L) Dunal. Arch Bus Res. 2015;3(2):179.